FEB 25 2014

510(k) SUMMARY

510(k) Notification K K133137

GENERAL INFORMATION

Applicant:
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Contact Person:
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U.S.A.
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Date Prepared: February 18, 2004

DEVICE INFORMATION

Trade Name:
ciSNaP® Closed Incision System

Generic/Common Name:
Non-powered suction apparatus device intended for negative pressure wound therapy

Classification:
21 CFR§878.4683, Class II

Product Code:
OKO

PREDICATE DEVICE(S)

- Spiracur Inc. CI-SNaP® Wound Care System (K111006)
- KCI USA, Inc. Prevena™ Incision Management System (K100821)
- Argentum International, LLC Silverlon™ Contact Wound Dressing (K981299)
- Select Fabricators, Inc. Ag MedTex Wound Dressing (K040518)

INTENDED USE

The ciSNaP® Closed Incision System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of small amounts of exudate from surgical incisions that continue to drain following sutured or stapled closure.

PRODUCT DESCRIPTION

The ciSNaP® Closed Incision System ("ciSNaP System") is a new addition to Spiracur Inc.'s ("Spiracur") family of negative pressure wound management devices. The ciSNaP System is a portable, non-powered, disposable Negative Pressure Wound Therapy ("NPWT") system that is intended for wound management through the removal of small amounts of exudate from surgically closed incisions. The ciSNaP System utilizes the concept of forced expansion of volume to produce negative pressure at the closed incision. The ciSNaP System can be applied in the sterile field. The ciSNaP System has no electrically powered parts and is disposable after use. Additionally, it is capable of delivering negative pressure wound therapy at a near-constant pressure level over several days without any required adjustments by the patient or clinician. The dressing component of the ciSNaP System incorporates an antimicrobial interface.

SUBSTANTIAL EQUIVALENCE

The indications for use for the ciSNaP® Closed Incision System are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the ciSNaP® Closed Incision System is substantially equivalent to the predicate devices.

TESTING

All necessary bench testing was conducted on the ciSNaP System to ensure conformance to design specifications to support a determination of substantial equivalence to the predicate devices. As verified by performance testing, the ciSNaP System is substantially equivalent to the predicate devices in terms of both intended use and technology, and the ciSNaP System is as safe and effective for delivery of negative pressure wound therapy.

Nonclinical Testing Summary:

The nonclinical, bench testing included:

- Verification testing was performed, and results demonstrate the device has appropriate design characteristics with respect to its intended use for delivery of negative pressure wound therapy;
- Biocompatibility testing according to ISO 10993-1 standards was performed, and results demonstrate the device is biocompatible according to these standards;
- Packaging and shelf life testing was performed, and results demonstrate conformance to product specifications;
- Ion release rate testing was performed, and results demonstrate antimicrobial characteristics as measured by silver ion availability are not significantly different after aging during the continuous use period; and
- *In vitro* antimicrobial log reduction tests were conducted on samples of the silver-plated skin interface layer of the ciSNaP® Controlled Tension Relief Layer. Tests were conducted without application of negative pressure and exposed silver-plated samples to 10^6 CFU challenges of six species of microorganisms. Following inoculation, samples were tested for microbial counts after incubation in diluted nutrient broth for 1, 3 and 7 days. Mean log reduction values derived from microbial counts of silver plated samples at day 1, day 3 and day 7 as compared to their unplated controls are provided in the table below:

Challenge Organism	Mean Log Reduction		
	Day 1	Day 3	Day 7
Staphylococcus aureus [ATCC 6538]	>4.3	>4.4	>4.1
Methicillin-resistant *Staphylococcus aureus* (MRSA) [ATCC 33591]	>4.3	>4.3	4.2
Vancomycin-resistant *Enterococcus faecalis* (VRE) [ATCC 51575]	>4.5	>4.6	>4.6
Escherichia coli [ATCC 8739]	>4.4	>4.4	>4.3
Pseudomonas aeruginosa [ATCC 9027]	>4.1	>4.1	>4.4
Klebsiella pneumoniae [ATCC 4352]	>4.3	>4.2	>4.4
Candida albicans [ATCC 10231]	>4.3	>4.2	>4.1
Aspergillus brasiliensis [ATCC 16404]	3.2	3.2	3.6

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the ciSNaP System meet the established specifications necessary for consistent performance during its intended use.

SUMMARY

The ciSNaP System has the same intended use and technological characteristics as the predicate devices: the existing Spiracur CI-SNaP Wound Care System (K111006) and the KCI Prevena™ Incision Management System (K100821). The ciSNaP Controlled Tension Relief Layer has a similar intended use as the Argentum International, LLC Silverlon™ Contact Wound Dressing (K981299) and the Select Fabricators, Inc. Ag MedTex Wound Dressing (K040518) predicate devices, as silver dressings for use on incisions. The use of the Silverlon Contact Wound Dressing and Ag MedTex Wound Dressing under static conditions and the ciSNaP Controlled Tension Relief Layer under negative pressure conditions has no bearing on citing these non-negative pressure dressings as predicates for the silver plating and plating process, respectively. The nonclinical performance test results demonstrate the ciSNaP System performs equivalently to the predicate devices and is as safe and effective as the predicate devices. The antimicrobial testing results support that the ciSNaP System has the same antimicrobial agent characteristics as the Prevena™ Incision Management System. Both the ciSNaP antimicrobial fabric and the Select Fabricators Ag MedTex Wound Dressing utilize the same basic chemical principles for the antimicrobial agent coating process. As verified by performance testing, any differences in technological characteristics do not raise any new issues of safety and effectiveness with regard to device operation, use, or its antimicrobial properties. Therefore, the collective results of nonclinical testing demonstrate that the ciSNaP System is substantially equivalent to the predicate devices in terms of both intended use and technology, and that the ciSNaP System is as safe and effective for delivery of negative pressure wound therapy.

CONCLUSION

The ciSNaP System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Spiracur, Incorporated
% Lori E. Adels, Ph.D.
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Sunnyvale, California 94085

Re: K133137
Trade/Device Name: ciSNaP® closed Incision System
Regulation Number: 21 CFR 878.4683
Regulation Name: Non-Powered suction apparatus device intended for negative pressure wound therapy
Regulatory Class: Class II
Product Code: OKO
Dated: January 10, 2014
Received: January 13, 2014

Dear Dr. Adels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133137

Device Name: ciSNaP® Closed Incision System

Indications For Use:

The ciSNaP® Closed Incision System is indicated for patients who would benefit from wound management via the application of negative pressure, particularly as the device may promote wound healing through the removal of small amounts of exudate from surgical incisions that continue to drain following sutured or stapled closure.

Prescription Use _X_ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S